EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Jill A. Jacobson on October 15, 2004.

2. The application has been amended as follows:

The claims have been amended as follows:

Claim 1 (previously presented): An isolated monoclonal anti-idiotype antibody 11D10 produced by hybridoma cell line ATCC No. HB 12020.

Claim 2 (currently amended): ~~The~~ A labeled antibody comprising the antibody of claim 1, ~~further comprising a~~ wherein said label is capable of producing a detectable signal.

Claim ~~3~~ 14 (previously presented): A hybridoma cell line designated ATCC No. HB 12020.

Claim ~~4~~ 16 (previously presented): A purified antibody having all the identifying characteristics of antibody produced by a hybridoma cell line according to claim ~~3~~ 14.

Claim ~~5~~ 15 (original): A hybridoma having all the identifying characteristics of a cell of the hybridoma cell line according to claim ~~3~~ 14.

Claims 6-19 (canceled)

Claim 23 (currently amended): A polypeptide having immunological activity of anti-idiotype antibody 11D10, wherein the polypeptide comprises an immunoglobulin variable region containing three light chain complementarity determining regions (CDRs) of anti-idiotype antibody 11D10, and an immunoglobulin variable region containing three heavy chain CDRs of anti-idiotype antibody 11D10, wherein anti-idiotype antibody 11D10 is produced by the hybridoma cell line designated ATCC No. HB 12020 ~~wherein the light chain variable region amino acid sequence is contained in an antibody produced by a hybridoma cell line designated ATCC NO. HB 12020, and wherein the heavy chain variable region amino acid sequence is contained in an antibody produced by a hybridoma cell line designated ATCC NO. HB 12020~~, and wherein the immunological activity of the polypeptide is an ability to stimulate a specific immune response against human milk fat globule (HMFG).

Claims 21-22 (canceled)

Claim 24 (previously presented): The polypeptide of claim 23, wherein the light chain variable region amino acid sequence is contained in SEQ ID NO:2 and the heavy chain variable region amino acid sequence is contained in SEQ ID NO:4.

Claims 24-25 (canceled)

Claim 25 (previously presented): The polypeptide of claim 23, wherein the polypeptide contains a sequence of at least 2 contiguous amino acids which are identical in forward or reverse orientation to 2 contiguous amino acids of a sequence in human mucin from human milk fat globule (HMFG), wherein said HMFG sequence is contained in SEQ ID NO:33.

Claim 35 (original): A fusion polypeptide comprising the polypeptide of claim 23.

Claim 37 (previously presented): The fusion polypeptide of claim 35 further comprising a cytokine.

Claim 38 (previously presented): The fusion polypeptide of claim 37, wherein the cytokine is granulocyte macrophage colony stimulating factor.

Claim 39 (previously presented): The fusion polypeptide of claim 37, wherein the cytokine is interleukin 2.

Claim 31 (canceled)

Claim 40 (currently amended): The fusion polypeptide of claim 35, wherein the immunoglobulin variable region of the polypeptide of claim 23, containing three CDRs from the light chain variable region of anti-idiotype antibody 11D10, and the immunoglobulin variable region of the polypeptide of claim 23, containing three CDRs from the heavy chain variable region of anti-idiotype antibody 11D10, are linked by a linker polypeptide of about 5 to 20 amino acids.

Claim 42 (previously presented): The fusion polypeptide of claim 35, comprising the light chain variable region and the heavy chain variable region of anti-idiotype antibody 11D10, wherein the light chain variable region and the heavy chain variable region are contained in SEQ ID NO:2 and SEQ ID NO:4, respectively.

Claim 44 (previously presented): The fusion polypeptide of claim 35 further comprising a heterologous immunoglobulin constant region.

Claim 46 (currently amended): A humanized antibody comprising three CDRs from the light chain variable region of antibody 11D10, three CDRs from the heavy chain variable region of antibody 11D10, and a constant region that is a human sequence, wherein antibody 11D10 is produced by the hybridoma cell line designated ATCC No. HB 12020, and wherein the humanized antibody is able to stimulate a specific immune response against human milk fat globule (HMFG), ~~wherein the light chain variable region amino acid sequence is contained in an antibody produced by a hybridoma cell line designated ATCC No. HB 12020, and wherein the heavy chain variable region~~

~~amino acid sequence is contained in an antibody produced by a hybridoma cell line designated ATCC No. HB 12020~~.

Claim ~~36~~ 26 (original): A polymeric 11D10 polypeptide comprising a plurality of the polypeptide of claim ~~20~~ 23.

Claim ~~37~~ 3 (currently amended): A composition comprising <u>the</u> anti-idiotype antibody ~~11D10~~ of claim 1 and a pharmaceutically acceptable excipient.

Claim 38 (canceled)

Claim ~~39~~ 55 (currently amended): A composition comprising a pharmaceutically acceptable excipient and a polypeptide having immunological activity of anti-idiotype antibody 11D10, wherein the polypeptide comprises an immunoglobulin variable region containing three light chain complementarity determining regions (CDRs) of <u>anti-idiotype</u> antibody 11D10, and an immunoglobulin variable region containing three heavy chain CDRs of <u>anti-idiotype</u> antibody 11D10, <u>wherein anti-idiotype antibody 11D10 is produced by the hybridoma cell line designated ATCC No. HB 12020</u> ~~wherein the light chain variable region amino acid sequence is contained in an antibody produced by a hybridoma cell line designated ATCC NO. HB 12020, and wherein the heavy chain variable region amino acid sequence is contained in an antibody produced by a hybridoma cell line designated ATCC NO. HB 12020~~, and wherein the immunological activity of the polypeptide is an ability to stimulate a specific immune response against human milk fat globule (HMFG).

Claim ~~40~~ 7 (currently amended): An immunogenic composition comprising <u>the</u> anti-idiotype antibody ~~11D10~~ of claim 1 and a pharmaceutically acceptable excipient.

Claim 41 (canceled)

Claim ~~42~~ 33 (previously presented): An immunogenic composition comprising the polypeptide of claim ~~20~~ 23 and a pharmaceutically acceptable excipient.

Claim ~~43~~ 8 (previously presented): The immunogenic composition of claim ~~40~~ 7, further comprising an adjuvant.

Claims 44-45 (canceled)

Claim ~~46~~ 10 (currently amended): A method of eliciting an immune response in an individual with advanced human milk fat globule associated disease comprising the step of administering an effective amount of ~~monoclonal~~ the anti-idiotype antibody ~~11D10~~ of claim 1 to the individual.

Claim ~~47~~ 9 (currently amended): A method of eliciting an immune response in an individual with advanced human milk fat globule associated disease comprising the step of administering an effective amount of the ~~vaccine~~ immunogenic composition of claim ~~43~~ 8 to the individual.

Claim ~~48~~ 11 (original): The method of claim ~~46~~ 10, wherein the advanced human milk fat globule associated disease is breast cancer.

Claim ~~49~~ 4 (currently amended): A method for ~~removing~~ promoting clearance of a labeled anti-human milk fat globule (HMFG) antibody that binds to the antibody of claim 1 from the circulation or tissues of an individual who has received [[a]] the labeled anti-HMFG antibody, comprising administering ~~monoclonal~~ the antibody ~~11D10~~ of claim 1 to the individual.

Claim 50 (canceled)

Claim ~~51~~ 5 (currently amended): A method for detecting an anti-human milk fat globule immunological response in an individual comprising the steps of (a) contacting a biological sample from the individual with the monoclonal anti-idiotype antibody 11D10 of claim 1 under conditions that permit formation of a stable complex between the monoclonal anti-idiotype antibody ~~11D10~~ and an antibody containing the paratope of the monoclonal anti-idiotype antibody ~~11D10~~; and (b) detecting any of the ~~stable~~ complexes

formed, wherein the presence of the complexes is indicative of the presence of an anti-human milk fat globule immunological response in the individual.

Claims 52-53 (canceled)

Claim 12 (currently amended): A kit comprising the anti-idiotype antibody ~~11D10~~ of claim 1 in suitable packaging.

Claim 13 (currently amended): The kit of claim 12, wherein the antibody ~~11D10~~ comprises a detectable label.

Claim 27 (previously presented): A kit comprising the polypeptide of claim 23 in suitable packaging.

Claims 57-58 (canceled)

Claim 6 (currently amended): A composition comprising an effective amount of the anti-idiotype antibody of claim 1, wherein an effective amount is an amount sufficient to elicit an anti-human milk fat globule immune response.

Claim 17 (previously presented): A composition comprising an effective amount of the antibody of claim 16, wherein an effective amount is an amount sufficient to elicit an anti-human milk fat globule immune response.

Claim 28 (previously presented): A composition comprising an effective amount of the polypeptide of claim 23, wherein an effective amount is an amount sufficient to elicit an anti-human milk fat globule immune response.

Claim 56 (previously presented): The composition of claim 55, wherein the specific immune response comprises production of HMFG-specific antibody.

Claim 57 (previously presented): The composition of claim 55, wherein the specific immune response comprises production of HMFG-specific T cells.

Claim ~~64~~ 47 (previously presented): The humanized antibody of claim ~~35~~ 46, wherein the specific immune response comprises production of HMFG-specific antibody.

Claim ~~65~~ 48 (previously presented): The humanized antibody of claim ~~35~~ 46, wherein the specific immune response comprises production of HMFG-specific T cells.

Claim 66 (canceled)

Claim ~~67~~ 45 (previously presented): The fusion polypeptide of claim ~~34~~ 44, wherein the immunoglobulin constant region is human.

Claim ~~68~~ 34 (previously presented): The immunogenic composition of claim ~~42~~ 33, further comprising an adjuvant.

Claim ~~69~~ 18 (previously presented): The purified antibody of claim ~~1~~ 16, said antibody comprising the sequence of SEQ ID NO:2.

Claim ~~70~~ 19 (previously presented): The purified antibody of claim ~~1~~ 16, said antibody comprising the sequence of SEQ ID NO:4.

Claim ~~71~~ 43 (currently amended): The fusion polypeptide of claim ~~33~~ 42, wherein the light chain variable region and the heavy chain variable region ~~of antibody 11D10~~ are joined by a linker polypeptide of about 5 to 20 amino acids.

Claim ~~72~~ 49 (previously presented): The humanized antibody of claim ~~35~~ 46, wherein the framework regions are human sequences.

Claim ~~73~~ 58 (currently amended): A humanized antibody comprising three CDRs from the light chain variable region of antibody 11D10, three CDRs from the heavy chain variable region of antibody 11D10, and framework regions that are human sequences, wherein antibody 11D10 is produced by the hybridoma cell line designated ATCC No. HB 12020, and wherein the humanized antibody is able to stimulate a specific immune response against human milk fat globule (HMFG).

Claim 74 (previously presented): A composition comprising the purified antibody of claim 1 and a pharmaceutically acceptable excipient.

Claim 75 (previously presented): A composition according to claim 74, wherein the composition is immunogenic.

Claim 76 (previously presented): A composition according to claim 75, further comprising an adjuvant.

Claim 77 (canceled)

Claim 78 (previously presented): A fusion polypeptide according to claim 27, wherein the amino acid sequences of the light chain variable region and the heavy chain variable region are contained in SEQ ID NO:2 and SEQ ID NO:4, respectively.

Claim 79 (previously presented): A fusion polypeptide according to claim 32, wherein the linker polypeptide comprises the amino acid sequence $(GGGGS)_3$ (SEQ ID NO:35).

Claim 80 (previously presented): A humanized antibody according to claim 35, wherein the light chain variable region of antibody 11D10 and the heavy chain variable region of antibody 11D10 are contained in SEQ ID NO:2 and SEQ ID NO:4, respectively.

Claim 81 (previously presented): A composition comprising the humanized antibody of claim 36 and a pharmaceutically acceptable excipient.

Claim 82 (previously presented): A composition according to claim 81, wherein the composition is immunogenic.

Claim 83 (previously presented): A composition according to claim 82 further comprising an adjuvant.

Claim 84 (currently amended): A humanized antibody comprising three CDRs from the light chain variable region of antibody 11D10, three CDRs from the heavy chain variable region of antibody 11D10, and framework regions that are human sequences, wherein

antibody 11D10 is produced by the hybridoma cell line designated ATCC No. HB 12020, wherein the humanized antibody is able to stimulate a specific immune response against human milk fat globule (HMFG), and wherein the light chain variable region of antibody 11D10 and the heavy chain variable region of antibody 11D10 are contained in SEQ ID NO:2 and SEQ ID NO:4, respectively.

Claim ~~85~~ 62 (previously presented): A composition comprising the humanized antibody of claim ~~84~~ 60 and a pharmaceutically acceptable excipient.

Claim ~~86~~ 63 (previously presented): A composition according to claim ~~85~~ 62, wherein the composition is immunogenic.

Claim ~~87~~ 64 (previously presented): A composition according to claim ~~86~~ 63, further comprising an adjuvant.

Claim ~~88~~ 65 (previously presented): An antibody comprising a light chain variable region amino acid sequence contained in SEQ ID NO:2 and a heavy chain variable region amino acid sequence contained in SEQ ID NO:4, wherein the antibody is able to stimulate a specific immune response against human milk fat globule (HMFG).

Claim ~~89~~ 66 (previously presented): A composition comprising the antibody of claim ~~88~~ 65 and a pharmaceutically acceptable excipient.

Claim ~~90~~ 67 (previously presented): A composition according to claim ~~89~~ 66, wherein the composition is immunogenic.

Claim ~~91~~ 68 (previously presented): A composition according to claim ~~90~~ 67, further comprising an adjuvant.

Claim ~~92~~ 69 (currently amended): An isolated antibody comprising three CDRs from the light chain variable region of anti-idiotype antibody 11D10 and three CDRs from the heavy chain variable region of anti-idiotype antibody 11D10, wherein anti-idiotype antibody 11D10 is produced by the hybridoma cell line designated ATCC No. HB

12020, wherein the CDRs from the light chain variable region are contained in SEQ ID NO:2 and the CDRs from the heavy chain variable region are contained in SEQ ID NO:4, and wherein the antibody is able to stimulate a specific immune response against human milk fat globule (HMFG).

Claim 91 (previously presented): A composition comprising the antibody of claim 69 and a pharmaceutically acceptable excipient.

Claim 92 (previously presented): A composition according to claim 71, wherein the composition is immunogenic.

Claim 93 (previously presented): A composition according to claim 72, further comprising an adjuvant.

Claim 96 (previously presented): A composition comprising the polypeptide of claim 23 and a pharmaceutically acceptable excipient.

Claim 97 (canceled)

Claim 98 (previously presented): A polypeptide comprising an immunoglobulin variable region containing three light chain complementarity determining regions (CDRs) of antibody 11D10, or an immunoglobulin variable region containing three heavy chain CDRs of antibody 11D10, wherein antibody 11D10 is produced by a hybridoma cell line designated ATCC NO. HB 12020.

Claim 99 (previously presented): A composition comprising the polypeptide of claim 74 and a pharmaceutically acceptable excipient.

Claim 100 (previously presented): A polypeptide according to claim 74, comprising an immunoglobulin variable region containing the three light chain CDRs of antibody 11D10.

Claim 101 (previously presented): A polypeptide according to claim 98, comprising an immunoglobulin variable region containing the three heavy chain CDRs of antibody 11D10.

Claim 102 (previously presented): A polypeptide according to claim 98, wherein the light chain variable region is contained in SEQ ID NO:2.

Claim 103 (previously presented): A polypeptide according to claim 98, wherein the heavy chain variable region is contained in SEQ ID NO:4.

Claim 104 (previously presented): A polypeptide comprising an immunoglobulin variable region containing three light chain complementarity determining regions (CDRs) of antibody 11D10 and an immunoglobulin variable region containing three heavy chain CDRs of antibody 11D10, wherein antibody 11D10 is produced by a hybridoma cell line designated ATCC NO. HB 12020, and wherein the light and heavy chain variable region sequences are contained in SEQ ID NO:2 and SEQ ID NO:4, respectively, and wherein the antibody is able to stimulate a specific immune response against human milk fat globule (HMFG).

Claim 105 (previously presented): A method of eliciting an immune response in an individual with advanced human milk fat globule associated disease comprising the step of administering an effective amount of an antibody according to claim 35 to the individual.

Claim 106 (previously presented): A method of eliciting an immune response in an individual with advanced human milk fat globule associated disease comprising the step of administering an effective amount of an antibody according to claim 78 to the individual.

Claim 107 (previously presented): A method of eliciting an immune response in an individual with advanced human milk fat globule associated disease comprising the step

of administering an effective amount of an antibody according to claim 84 to the individual.

Claim 108 (previously presented): A method of eliciting an immune response in an individual with advanced human milk fat globule associated disease comprising the step of administering an effective amount of an antibody according to claim 92 to the individual.

Claim 109 (previously presented): A method of eliciting an immune response in an individual with advanced human milk fat globule associated disease comprising the step of administering an effective amount of a polypeptide according to claim 20 to the individual.

Claim 110 (previously presented): A method of eliciting an immune response in an individual with advanced human milk fat globule associated disease comprising the step of administering an effective amount of a polypeptide according to claim 104 to the individual.

Claims 111-124 (canceled)

Claim 125 (new): The polypeptide of claim 20, wherein the specific immune response comprises production of HMFG-specific antibodies.

Claim 126 (new): The polypeptide of claim 20, wherein the specific immune response comprises production of HMFG-specific T cells.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.